State of California—Health and Human Services Agency
Committee for the Protection of Human Subjects

CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

GAVIN NEWSOM
Governor

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CalHHS)

Friday, March 1, 2024
9:00 a.m.

Zoom:
CPHS March 1, 2024, Full Committee Meeting

Meeting ID: 160 566 9170
Passcode: 547576

Location:
1215 O Street,
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Meeting ID: 1605669170

MINUTES

Members
Darci Delgado, PsyD. (Interim Chair)
Larry Dickey, MD, MPH, Vice Chair
Juan Ruiz, MD, DrPH, MPH
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Catherine Hess, PhD
Carrie Kurtural, JD
Laura Lund, MA
Philip Palacio, EdD, MS
John Schaeuble, PhD, MS
Allen Azizian, PhD
Maria Ventura, PhD
Jonni Johnson, PhD

Remote Attendees
Larry Dickey, MD, MPH
Allen Azizian, PhD
Maria Dinis, PhD, MSW
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

Administrator
Agnieszka Rykaczewska

CDII
John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director
Jennifer Schwartz, Chief Council

Committee Members Present In Person:
Darci Delgado, PsyD.
Catherine Hess, PhD
Carrie Kurtural, JD
Laura Lund, MA
Philip Palacio, EdD, MS
John Schaeuble, PhD, MS
Maria Ventura, PhD
Jonni Johnson, PhD

Committee Members Present Remotely:
Larry Dickey, MD, MPH
Juan Ruiz, MD, DrPH
Allen Azizian, PhD
Maria Dinis, PhD, MSW
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW

California Health and Human Services Staff Present:
Marko Mijic, Undersecretary

CPHS Staff Present:
Agnieszka Rykaczewska
Lucila Martinez
Sussan Atifeh
Nicholas Zadrozna

CDII Staff Present Remotely:
John Ohanian, Director
Jennifer Schwartz, Chief Legal Counsel

A. Welcome and Chair Updates

I. Dr. Delgado conveyed her appreciation to all committee members for their presence in today's full board committee meeting, both in person and remotely, ensuring the establishment of quorum.

II. The Committee for the Protection of Human Subjects (CPHS) administrative team has identified six training modules within the Collaborative Institutional Training Initiative (CITI) Program, which will be accessible to all committee members. CPHS is currently in the procurement process for the CITI Program. Upon availability of the trainings, an email notification will be sent out to all committee members.

B. Common Rule and Information Privacy Act Regulations and Applications

1) **Presentation of Legal Analysis of Regulations by CDII Legal Counsel**

Dr. Delgado, CPHS Interim Chair, introduced Jennifer Schwartz, the chief legal counsel for the Center for Data Insights and Innovations (CDII), to present the flow chart created by CPHS administrative staff. This flow chart aimed to elucidate the legal authority of CPHS and aid researchers and committee members in understanding the appropriate review processes for different project types. Jennifer Schwartz explained how CPHS's legal authority and jurisdiction were established, citing the FederalWide Assurance (FWA) with the Federal Government, which governs the Institutional Review Board (IRB) activities of CPHS under the common rule. Additionally, Jennifer highlighted CPHS's role as a committee for reviewing projects under the Information Practices Act (IPA), particularly requests for state data. Moreover, Jennifer noted the introduction of CPHS to CDII and referenced a new statute related to CPHS, as submitted by Dr. Dinis.

One category of review pertains to requests solely for state data, falling under CPHS's jurisdiction as outlined in the IPA criteria (Civil Code section 1798.24(t)). Another category involves research involving human subject participants, where CPHS functions as an IRB under the common rule and the FWA (45 C.F.R. sections). The third scenario encompasses projects involving both human subjects and state data, requiring review based on criteria from both the common rule and the IPA. Finally, if a research project does not involve state data or human subject contact, CPHS does not have purview.

Following Jennifer Schwartz's explanation of the flow chart, Dr. Dinis highlighted a section of the FWA: CPHS's election to review all research, regardless of qualification under Federal Government guidelines, by “checking the box”. Examining the updated FWA under section 4(b), it states, "Optional": This Institution elects to apply the following to all of its human subject research regardless of the source of support, except for research that is covered by a separate assurance." Dr. Dickey clarified that the new FWA has an optional statement that implies the institution's choice to apply the common rule to human subject research, irrespective of funding sources. Jennifer Schwartz affirmed this interpretation, concluding that when the IRB reviews human subjects research under the common rule, it indicates agreement to utilize the common rule for such reviews, as articulated in option B. This statement met with no opposition.

2) Highlights of Additional Resources on IPA and Common Rule Regulations

Ms. Lund raised a query regarding Title 45, emphasizing that besides data collected directly from or used to contact human subjects, certain research projects are recognized as data-only endeavors. These projects involve confidential private information, as outlined in the Office for Human Protections (OHRP) guidelines document she distributed. Ms. Lund referred specifically to "Chart 01: Is an Activity Human Subject Research Covered By 45 CFR Part 46" on the OHRP website, noting a section concerning the collection of identifiable private information. She expressed concern that the flow chart shared by Jennifer Schwartz might not fully address situations where researchers obtain identifiable private information without contacting human subjects. Dr. Dickey suggested that the flow chart did address this scenario, but Ms. Lund argued that the current decision tree does not encompass all IRB roles, particularly when CPHS acts as the IRB. The committee requested additional guidance on this decision point, with Ms. Kurtural proposing a thorough examination of federal regulations for clarification. Jennifer Schwartz agreed, emphasizing the need for additional legal analysis to grasp the law's intent.

Dr. Dinis shared an email received from the Office for Human Research Protections (OHRP) at the US Department of Health and Human Services (HHS). In her inquiry, Dr. Dinis raised

concerns about conflicts of interest and FederalWide Assurance (FWA) between CDII and CPHS, highlighting CDII's focus on expediting data requests to researchers. Dr. Delgado acknowledged Dr. Dinis's concerns and recommended addressing them offline with CDII staff and the director. Jennifer Schwartz reassured Dr. Dinis that CDII's role is to inform the committee of its legal authority, emphasizing that decisions outside this authority may result in personal liability for board members. Dr. Delgado reiterated her availability to discuss individual concerns offline and encouraged committee members to seek legal advice from CDII while maintaining their independence.

Dr. Dickey referenced approved policies and procedures by the secretary of the California Health and Human Services Agency (CalHHS), emphasizing the necessity of adhering to federal regulations governing IRB operations. Ms. Lund sought clarification on when legal advice from CDII is advisory or prescriptive, expressing concerns about decision-making processes and the involvement of committee members.

Dr. Dinis presented OHRP's response regarding data repository oversight, stressing the complexity arising from California's status and CPHS's approval requirement. Dr. Dickey referenced federal regulations allowing IRBs to review data centers' protocols and procedures but clarified that CPHS does not review all state department data centers.

Ms. Kurtural shared agreements between her department and CPHS, outlining their role in reviewing research projects involving state data, despite not being data repositories themselves. Dr. Dickey noted changes in regulations regarding data release and research engagement, highlighting the complexities involved.

Ms. Lund suggested a review of policies and procedures after legal analysis of federal regulations, supported by Ms. Kurtural. Dr. Schaeuble shared a personal example of obtaining a Privacy agreement during his wife's surgery. The Privacy agreement included one generalized statement buried in the document that allows for sharing her health data for any research. The statement was very nonspecific and doesn't reference what type of research the data is used for. Dr. Schaeuble noted that the consent form was filled out during a stressful circumstance the morning before surgery, with no real information provided about any of the documents, this would not be considered an informed volunteer consent situation.

3) **Discussion of Application of IPA and Common Rule Regulation**

Dr. Dickey expressed empathy towards Dr. Schaeuble, recognizing the unpleasantness of the experience described by Dr. Schaeuble. Dr. Dickey then mentioned, "In 2018, the Office for Human Research Protections (OHRP) introduced something into the Common Rule that allows IRBs of the releasing organizations to conduct limited reviews of data centers, focusing primarily on the adequacy of their broad consent procedures. These procedures concern the consent provided by individuals for the release of their data, assessing whether the established procedures and the obtained broad consent are adequate for data release. Dr. Dickey said, under the Common Rule we can review data centers for the adequacy of their consent, but we cannot do that project by project, considering the complexity and the expectation that the IRB of the receiving organization will also review the data usage." Concluding his point, Dr. Dickey raised a policy question for the agency: Should the IRB of the releasing organizations engage in

this limited review of data centers to ensure the adequacy of consent procedures as part of our oversight responsibilities?

Dr. Delgado mentioned, Dr. Dinis comments on the board's perceived lack of independence deeply resonated with her, highlighting the critical nature of maintaining autonomy in board decisions. In response, she requested John Ohanian, the director of CDII, and his superior, Marko Mijic, the Under Secretary to join the meeting and openly discuss these concerns to ensure that higher-ups fully grasp the importance of the board's independence in a transparent manner. She encouraged attendees to prepare their thoughts during a brief pause before John Ohanian, CDII Director, and Marko Mijic, Undersecretary of CalHHS, to join, emphasizing the value of expressing these concerns directly to them for a comprehensive understanding of the board's stance on independence.

Dr. Schaeuble mentioned, “When we are reviewing projects under the Information Practices Act (IPA), the language specifies that a minimum set of criteria needs to be reviewed. However, if we truly treat it as a minimum instead of maximum, and do not include evaluating the consent process as part of our review and do not consider individuals’ consent when providing their information, we are essentially granting a blanket waiver of informed consent for data-only projects reviewed solely under the IPA, which is not appropriate. In some instances, especially during the past year, we received projects proposing specific uses of data and requesting sensitive information, where overlooking consent is clearly inappropriate. I’m not willing as a person to operate under a policy that waives informed consent for all data-only projects; that is not reasonable to me.”
Ms. Kurtural mentioned, “Having observed various projects from a ground-floor perspective, my primary concern lies in the mismatching and connecting of data sets. These instances particularly capture my attention during reviews, suggesting a need for a more nuanced approach. One critical consideration is the requirement for informed consent, which might be necessary for some projects with significant privacy implications. However, understanding the impracticality of obtaining consent from extensive populations (e.g., half a million people), we can review them in a full board meeting instead of reviewing them through an expedited review within the framework of the Information Practices Act (IPA) as a minimum requirement.”

Ms. Lund mentioned, “one of the things that we as committee don't do often enough is the acknowledgement of the informed consent issues. Rather than disallowing research due to the impracticality of obtaining informed consent from a large number of participants, such as 500,000 individuals, we should consider the significance of the research itself. If a study is deemed sufficiently important, it may justify granting a waiver of informed consent. This waiver indicates that the committee has thoroughly reviewed all the aspects of the study and made a determination that it is important enough to proceed even though the consent may have not been adequately included all the issues that Dr. Schaeuble just raised.”

Ms. Kurtural mentioned, “What you are describing is a creative solution, and to get there, we just need to have the CDII legal group to do a deeper dive into the legislative

intent of the relevant section then we can start discussing it and that's the flexibility that we would have as an independent board."

Dr. Schaeuble mentioned, say "It seems to me that there are a whole range of possibilities here, and we really should not be ruling out any of them. There may be many projects for which waiving informed consent seems fairly reasonable. There may be others that definitely should be discussed by the full board. There should not be a presumption that just because researchers have requested data, approval is to be assumed. There may be cases where we may have an obligation to change what is to be done with the data. In rare instances, if the researchers cannot come up with satisfactory ways to resolve the conflict between what they want to do and the absence of consent, we should be able to decline the project. We should be encouraged to use our professional expertise to make the appropriate judgments when reviewing projects rather than adhering rigidly to a predefined set of criteria."
Dr. Dickey mentioned, "The common rule is quite clear that we don't have to review data releases under the common rule, but we can review data centers. Therefore, it's imperative for our legal team to examine this aspect closely. Additionally, there's a need to delve into the Information Practices Act (IPA), particularly the phrase 'at a minimum' to clarify its implications. This wording suggests that certain projects require review under the Common Rule, indicating an intent not to limit our review scope solely to the IPA. It's crucial for us to understand the background principles of both the Common Rule and the IPA to guide our review process effectively."

CDII Chief Counsel, Jennifer Schwartz mentioned, "I would like to clarify the guidance I provided previously, especially regarding our discussions about the "at a minimum" language within the Information Practices Act (IPA). During our previous conversation, we went through the statute's text, which stipulates that certain criteria must be considered at a minimum when approving state data research. My advice was nuanced: I suggested these are at minimum of what the Board should consider in terms of approving the State data research, but because of the way that this statute is written, the Board should consider things that are similar to those criteria rather than bringing in and importing things that are outside of those criteria. I am willing to present the statute again for further discussion. We can also take a legal look at it and provide written clarification to the Board. This would allow the Board to see exactly what it says and raise any questions for further discussion."

Jennifer Schwartz shared the screen and explained about Information Practices Act (IPA). She mentioned, there are two pieces to the criteria in the IPA, and the first piece outlined in § 1798.24 subdivision (t)(1), mandates that the approval shall include a review and determination that all the following criteria have been satisfied:
(A)The researcher has provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.
(B)The researcher has provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research project unless the

researcher has demonstrated an ongoing need for the personal information for the research project and has provided a long-term plan sufficient to protect the confidentiality of that information.

(C)The researcher has provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner, not approved in the research protocol, except as required by law or for authorized oversight of the research project.”

The next piece refers to the “at the minimum” and mandates that the CPHS or institutional review board shall, at a minimum, accomplish all of the following as part of its review and approval of the research project for the purpose of protecting personal information held in agency databases:

(A)Determine whether the requested personal information is needed to conduct the research.
(B)Permit access to personal information only if it is needed for the research project.
(C)Permit access only to the minimum necessary personal information needed for the research project.
(D)Require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.
(E)If feasible, and if cost, time, and technical expertise permit, require the agency to conduct a portion of the data processing for the researcher to minimize the release of personal information.

Jennifer clarified her recommendation, emphasizing that the phrase "at a minimum" suggests the Board to consider specific criteria essential for its review process. Her advice centered on the interpretation of this directive to prioritize releasing the minimum necessary personal information for research objectives. This includes evaluating the potential for masking or anonymizing data to limit exposure and determining if personal information is essential for the research. She encouraged the Board to consider the essence of this in terms of how to import additional criteria for their review.

Dr. Schaeuble mentioned, “We are looking at the document here, and the initial sentences outline that the CPHS or institutional review board shall, at a minimum, accomplish all of the following as part of its review and approval of the research project for the purpose of protecting personal information held in agency databases. I would consider what I am hearing to be a very narrow interpretation, particularly regarding the protection of personal information, as opposed to a broader interpretation that would recognize the autonomy of people, ensuring they have the final say on how their personal information is used, and they can decide to share it with an agency with some initial understanding of the purposes for which that agency has requested the information, but they don't lose their rights to protect that personal information from other uses that they might not want. If that phrase is interpreted in a broader sense than what you were doing, then it accentuates the importance of consent in protecting

personal information. My question to you, Jennifer, concerns the legal implications of this broader interpretation. It certainly sounds like you are saying if committee members apply their professional expertise beyond the very narrow interpretation you're talking about, legal staff may not act to protect us, potentially exposing us to liability, and consequently, this might necessitate additional liability insurance for our volunteer contributions to the committee, implying further unreimbursed costs for our efforts." Jennifer Schwartz mentioned, "I want to address a misunderstanding regarding the committee members' perceptions. I never stated that the State would not defend your decisions. My comments were aimed at clarifying the legal jurisdiction and authority of the CPHS. What I said was that I'm informing you of what I believe the legal jurisdiction and legal authority of the CPHS is. Whether you will be sued, the potential for litigation exists, as anyone can sue anybody for any reason, a situation beyond my control. I could be sued tomorrow for something I may not have even done, and I can't prevent that. Whether the State will choose to represent is a totally different question. My advice to the committee has been based on my understanding and interpretation of the legal authority of the CPHS. What happens when a body acts in excess of their legal authority is that their decisions are often considered void as acting in excess of their authority, and then what would usually be something that is under the jurisdiction is outside of the jurisdiction. That is what I've been saying this time. I want to be very clear about that.

Dr. Delgado introduced Director John Ohanian, and Undersecretary Marko Mijic who joined the meeting to discuss the autonomy of the board. She mentioned, "Marko Mijic serves as the Undersecretary at the California Health & Human Services Agency. In this role, Marko oversees 12 departments and five offices one of which is Center for Data Insights and Innovation (CDII)."

Dr. Dinis mentioned, "Before CPHS being transferred under CDII, the question of the Board's independency was never an issue and I have felt a pressure because we are requested to consider the needs of researchers and approve their submitted projects as fast as possible, and it is contrary to what our role is as committee members. It seemed the guidance we get is not necessarily legal guidance and there is a certain amount of intimidation to me regarding being sued because of going outside of the legal context and it bothers me because I know it is ethics. I like to know how you are going to sue me on my ethics. I think there has been certain amount of pressure because the IRB and CDII are opposite of each other. CDII's role is to release data, but our goal is to ensure that the data is released properly. It is inappropriate to me, and it is like a conflict of interest that does not work."

Marko Mijic mentioned, "I struggle to see the conflict of interest. Our job, like yours, is to ensure government data is shared correctly, following state and federal laws, and our organization's standards. I don't see how our legal responsibilities as a state organization conflict with your duties as a board within this organization."

Dr. Dinis mentioned, “CDII is more protecting the researchers and their needs and interests, and not protecting members and the focus is on the researchers. We need to focus on the data, the human subjects, the vulnerable populations, and I think some of their data sets are exploiting and that is what I object.”

Dr. Dickey mentioned, “The Information Practices Act (IPA) is pretty narrow and designates certain criteria at a minimum we use to review data releases and those criteria are really restricted to ensure minimum necessary data has been requested by the researchers and the data should be adequately protected and secured. It does not address the ethical aspects of the projects like whether the informed consent obtained properly, or it is ethical to conduct such research.”

Marko Mijic explained the strategic reasons behind moving CPHS under the Center for Data Insights and Innovation (CDII) to make it the central hub for information. He mentioned, this move aimed to address the complexity of services provided to diverse groups, recognizing the interconnectedness of various programs such as Medicaid, CalFresh, and CalWORKS, etc. He emphasized on enhancing internal capacity to actively engage with the research community for informed policy and program development, rather than passively waiting for published studies. He highlighted the importance of creating a user-friendly environment for data access, adhering to research protocols aligned with IRB standards, and building trust within the community and the responsibility to ensure released information complies with legal standards, advocating for a holistic approach to handling data and research engagement.

Dr. Bazzano highlighted a difference in perspective regarding who the primary customer is; she mentioned for committee members in CPHS the primary customer is the research subject, not the researcher and the fundamental assumption at CPHS is to protect research subjects, which might lead to data not always being released, based on ethical considerations. She said these differing views and priorities can be potential sources of conflict. She also said that committee members’ purview in different settings, is becoming very narrowed, based on the interpretations that members had received from the legal Counsel which has been concerning.

Marko Mijic clarified that CDII’s role is not to release data, the role of CDII is to harness the data internally to help us internally figure out how we actually use that information to inform policy and programmatic development of our work across our organization. He also mentioned that the situation should not be seen as choosing between researchers or research subjects, but rather considering both interests together.

Ms. Kurtural expressed concerns from a legal standpoint about whether the committee members thoroughly examined Title 45 of the California Code of Federal Regulations, particularly section 46.102(E)(1), which deals with personally identifiable information and its legal implications. She suggested the need for a more detailed analysis, including a preemption analysis, to clarify the distinction between data-only projects and human subject research. She pointed out the potential for confusion in the regulations, especially regarding the handling of personally identifiable information and

biospecimens, and whether these apply strictly to clinical research or more broadly. She further investigation into how these issues are addressed in the Federal Register to better understand the legal requirements and possible exceptions for data handling and research projects.

Marko Mijic mentioned that the committee members can consult with legal counsel for their interpretations. However, it ultimately falls on the members to critically evaluate this advice and decide whether to act on it.

Ms. Lund agreed with what Dr. Bazzano mentioned and said that for committee members, the welfare of the research subjects takes priority which means sometimes we need to deny a project.

Marko Mijic said, “have one sole responsibility pursuant to the Statute and your responsibility as board is to solely focus on the subjects and that should be your responsibility and you have the authority to make an independent decision by focusing on your statutory report.”

Marko Mijic said, “I think it would be helpful for me to understand the path forward, because we do believe in a strong IRB and want a world-class IRB within our institution and we want people to come here to feel like they're getting world-class service, and they feel like they're actually coming to a place where something is being thoroughly vetted to understand whether or not a research project should be moving forward. Your role and responsibility over time has changed. You were solely focused for many years on real research where human subjects are actually involved. The whole edition of the release of data is a whole different element of your work, and I think that also needs to be looked at in terms of what is the role of this entity, and should it be focused also on the release of data as well as the use of human subjects in a particular research protocol? Those to me are two very different things, but I think that also is something we need to think about, whether or not we need to delve into clarification within the statutory framework of this work.”

Marko Mijic requested a copy of the letter that was sent to the federal government. He also urged the members to come together as a group to make a recommendation to him about how they want to proceed. He also said we might need to look at outside Counsel.

John Ohanian mentioned, “I've always tried to approach it from a standpoint that CDII and our team are a supportive role to the CPHS. I don't see CDII governing CPHS and I've tried to work with Dr. Dickey, Dr. Ruiz, and others in terms of seeing how we can provide additional supports to help you achieve your mission.”

Dr. Dickey mentioned, “After moving under CDII, Dr. Ruiz and I discussed with Marko Mijic the agency's limitations, particularly concerning perceptions of interference with individual project decisions and we largely clarified these concerns. However, the current issue is that the committee's Responsible Official, who is the Secretary, must

approve our policies and procedures. Federal law requires us to have these policies and procedures, which outline the committee's scope of authority. While the committee can make recommendations for what the committee's purview to be, ultimately, it's the Secretary who must approve it."

Dr. Schaeuble mentions "The second part of the conflict we are feeling is that the recently distributed policies and procedures manual incorporated some limitations on our approach, in particular with regard to reviews under the Information Practices Act – limitations that were never discussed with the committee but nonetheless were edited into the manual that was approved by the Secretary and then presented to the committee."
Marko Mijic acknowledged that the situation was unfair and should not have occurred. He encouraged committee members to specify desired changes and express any disagreements with previous modifications to the Policies and Procedures handbook as a concrete way towards progress. He committed to reviewing and endorsing proposals within his authority. He said, "As staff we need to make recommendations to you, and you need to vote on whether or not you approve the changes." He reassured that the Secretary would not ratify any changes met with dissent from the committee. He also highlighted the need to resolve any discrepancies before advancing the policies and procedures.

Marko requested that committee members review the handbook and submit a revised copy with suggested changes within the next 30 days. This would allow him to review and then present these amendments to the committee for a vote on their inclusion or exclusion before forwarding the document to the Secretary. He also mentioned the possibility of consulting with legal counsel or bringing in external legal assistance if necessary, expressing his willingness to facilitate this process.

Ms. Lund recommended reaching out to the Office for Human Research Protections (OHRP) as the federal guidance agency and Marko Mijic agreed.

Dr. Delgado emphasized the necessity of mapping out the decision-making process to encompass all critical discussions from the meeting. She highlighted the key points for consideration and potential action:

1. A deep dive with Counsel on reviewing Title 45 and OHRP guidance to resolve issue of reviewing data only projects under the Common Rule when acting as the IRB of record. The review should also explore if the Information Practices Act (IPA) restricts committee members from applying additional criteria. Additionally, the review should include the issue of data repositories.
2. What other criteria do we need to consider as a board when reviewing Information Practices Act (IPA) projects? The Board should explore and ascertain the possibility of consulting external legal counsel.

Dr. Delgado proposed that after a detailed legal consultation on these matters, the findings would be presented to the board for decision-making in a future meeting. This

step aligns with the Under Secretary's perspective that the board has the authority to make decisions after receiving recommendations from Legal team and decides whether any modifications to the Policies and Procedures handbook and the Decision Tree diagram are needed.

Steps 3 & 4 are dependent on the outcome of the legal review.
3. Are changes in the decision tree policy/procedure needed?
4. All will review the PP over the next weeks.

Dr. Bazzano requested more time to work on the Common App due to the intense pressure she and Dr. Schaeuble have been facing to complete it on schedule. She mentioned, the urgency came from the timelines provided by the Under Secretary, to better serve researchers, since the whole purpose of the Common App is making the process better for the researchers. Agnieszka Rykaczewska, the Deputy Director of the Insight Lab, agreed that the priority for developing the Common App should be reconsidered because its completion relies on the final decisions regarding the new priorities outlined during the meeting.

Dr. Dickey recommended to include the issue of data repositories in the key point number one and suggested asking legal to look at it since it is included in Common Rule as well.

Dr. Delgado requested committee members to make motions.

Ms. Lund moved, and Dr. Schaeuble seconded, the motion for the Committee to explore the integration of additional criteria in the evaluation of Information Practices Act (IPA) projects. This entails seeking guidance from external legal counsel to ascertain if the IPA restricts our ability to consider such criteria. Subsequently, the Committee will determine the appropriate criteria to be included in its review process.

Approved: Ms. Lund, Dr. Schaeuble, Dr. Dickey, Dr. Dinis, Ms. Kurtural, Dr. Palacio, Dr. Azizian, Dr. Ventura, Dr. Johnson, Dr. Bazzano.
Oppose: None.
Abstain: None.
Absent: Dr. Ruiz, Dr. Hess.

Ms. Lund moved, and Dr. Palacio seconded the motion for the Committee to seek outside legal counsel to review Title 45 and the Office for Human Research Protections (OHRP)'s guidance regarding when data-only projects should be reviewed under the Common Rule and when the Committee should review data repositories under the Common Rule.

Approve: Ms. Lund, Dr. Palacio, Dr. Dickey, Dr. Dinis, Ms. Kurtural, Dr. Schaeuble, Dr. Azizian, Dr. Ventura, Dr. Johnson, Dr. Bazzano.
Oppose: None.

Abstain: None.
Absent: Dr. Ruiz, Dr. Hess.

C. Amendments- Full Committee Review Required

None.

D. Public Comments

A member of the public in attendance expressed his gratitude towards the board, with a special commendation directed at Dr. Bazzano.

E. Next Meeting

The next CPHS full board meeting is scheduled for Friday, April 5, 2024.

F. Adjournment

The meeting was adjourned at 11:59 AM on March 1, 2024.